

**REMARKS**

Applicants respectfully request reconsideration of the present application. Claims 10 and 21 have been amended. Claims 1-9, 20 and 30 previously have been canceled. As such, claims 10-19, 21-29 and 31-40 are pending herein. No new matter has been added to the present application. Claims 10-19, 21-29 and 31-40 are believed to be in condition for allowance and such favorable action is respectfully requested.

**Claim Rejections – 35 U.S.C. § 103**

2. Claims 10-11, 14, 16-17, 19, 21, 24, 26, 27 and 29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,117,836 to Millar (the Millar Patent) in view of U.S. Patent No. 5,833,603 to Kovacs et al. (the Kovacs Patent) and in further view of U.S. Patent No. 4,904,237 to Janese (the Janese Patent). Applicants have amended claims 10 and 21. Amended claim 10 recites a method for monitoring the cerebral environment of a patient for prognosis comprising monitoring changes of the pH of the CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma. Claim 21 recites a method of monitoring at least one characteristic of CSF of a patient for prognosis comprising monitoring the pH of the CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma. Applicants submit that neither the Millar Patent, the Kovacs Patent nor the Janese Patent teach or suggest monitoring the pH of CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma.

The Millar Patent teaches a method for measuring intracranial fluid characteristics but does not teach or suggest monitoring the pH of CSF. The Kovacs Patent also does not teach monitoring the pH of the CSF within 48 hours of the initial to predict the outcome of the head

trauma. Rather, the Kovacs Patent teaches an implantable biosensing transponder for monitoring blood chemistry.

The Janese Patent also does not teach monitoring the pH of the CSF within 48 hours of the initial to predict the outcome of the head trauma. Applicants respectfully disagree that it would be obvious at the time the invention was made to monitor the cerebral spinal fluid at times of arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord to use the combination to predict the outcome of head trauma. There is no teaching or suggestion in the Janese Patent that monitoring the pH of CSF fluid within the initial 48 hours following the initial head trauma will be beneficial for predicting the outcome of the head trauma (e.g. whether or not the patient has a chance of recovery). The Janese Patent merely teaches that the pH is monitored. According to an embodiment of the present invention, monitoring the pH within the initial 48 hours following head trauma helps predict the outcome of head trauma. However, it is difficult to predict in the what measurements will be beneficial as diagnostic aids and when these measurements should be taken. So, while it might have been obvious to try to measure the pH of CSF fluid within the initial 48 hours following head trauma, there is no teaching or suggestion in the Janese patent that monitoring the pH of CSF within 48 hours following the initial head trauma would function as a diagnostic tool or aid the patient.

According to In re Antonie, obviousness cannot be based upon what a person skilled in the art might try or might find obvious to try, but rather must consider what the prior art would have led a person skilled in the art to do. 559 F.2d 618 (CCPA 1977). In this case, while it might have been obvious to try to measure the pH of CSF fluid within 48 hours following initial head trauma it was not known that measuring the pH of CSF within the initial

48 hours following head trauma would act as a diagnostic aid and help in predicting the outcome of head trauma.

As neither the Millar Patent, Kovacs Patent or the Janese Patent teach or suggest monitoring changes of the pH of CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma, Applicants request withdrawal of the rejection of claim 10 and 21 under 35 USC 103 (a). As claims 11, 14, 16-17, 19, 24, 26, 27 and 29 depend either directly or indirectly from independent claims 10 and 21, Applicants request withdrawal of the 103 rejection to these claims as well.

3. Claims 13 and 23 have been rejected under 35 USC 103(a) as being unpatentable over the Millar Patent in view of the Kovacs Patent further in view of the Janese Patent and further in view of U.S. Patent 5,830,188 to Abouleish (the Abouleish Patent). As discussed above the Millar Patent, the Kovacs Patent and the Janese Patent do not teach or suggest monitoring the pH of CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma. The Abouleish Patent also does not teach or suggest monitoring the pH of CSF the initial 48 hours following head trauma to predict the outcome of the head trauma. Rather, the Abouleish Patent teaches a curved cannula for continuous spinal anesthesia. As the Millar Patent, Kovacs Patent, Janese Patent and Abouleish Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma to predict the outcome of the head trauma, Applicants request withdrawal of the 103 rejection as to claims 13 and 23.

4. Claims 10-12, 15, 21-22, 25 have been rejected under 35 USC 103 (a) as being unpatentable over the Kovacs patent in view of U.S. Patent 4,903,707 to Knute et al. (the Knute patent) and in further view of the Janese Patent. With respect to amended independent

claims 10 and 21, as discussed above the Kovacs patent and Janese Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma. Further, the Knute Patent neither teaches nor suggests monitoring the pH of CSF within the initial 48 hours following head trauma to predict the outcome of the head trauma. Rather the Knute Patent teaches a ventricular catheter assembly having a catheter for insertion through an opening in a skull for monitoring a parameter of a brain in a living person.

As the Kovacs Patent, Janese Patent and the Knute Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma to predict the outcome of head trauma, Applicant requests withdrawal of the 103 rejection of claims 10 and 21. As claims 11-12, 15, 22 and 25 depend either directly or indirectly from claims 10 and 21, Applicants request withdrawal of the rejection as to these claims well.

5. Claims 18 and 28 have been rejected under 35 USC 103 (a) as being unpatentable over the Kovacs Patent in view of the Knute Patent in further view of the Janese Patent and in further view of the U.S. Patent 5,403,746 to Bentson et al. (the Bentson Patent) and Re 31,879 to Lubbers et al. (the Lubbers Patent). As discussed above, with respect to independent claims 10 and 21, the Kovacs Patent, the Knute Patent and the Janese Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma to predict the outcome of the head trauma. Further the Bentson Patent and the Lubbers Patent also fail to teach or suggest monitoring the pH of CSF 48 hours following the initial head trauma to predict the outcome of the head trauma. Rather, the Bentson Patent teaches an optical fluorescence based sensor for measuring the concentration of a gas in a medium which has improved drift stability. The Lubbers patent teaches a method and an arrangement for measuring the

concentration of gases in a sample including the generation of a monochromatic light beam having predetermined color characteristic.

As the Kovacs Patent, Knute Patent, Janese Patent, Benson Patent and Lubbers Patent neither teach nor suggest monitoring the pH of CSF 48 hours following the initial head trauma to predict the outcome of the head trauma, Applicants request withdrawal of the 103 rejection of claims 18 and 28 as they depend either directly or indirectly from claims 10 and 21.

6. Claims 31, 34, 36 and 39 have been rejected under 35 USC 103(a) as being unpatentable over the Millar Patent in view of the Kovacs Patent and further in view of U.S. Patent 6,049,727 to Crothall (the Crothall Patent). As stated in the Office Action dated December 13, 2003, the combination of the Millar Patent and the Kovacs Patent does not teach at least one sensor capable of sensing pH located within a porous sheath.

If a combination of prior art references destroys the purpose or function of the prior art reference or references, one of ordinary skill in the art would not have found a reason to make the combination. In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). Combining the Crothall Patent with the Millar Patent destroys the intended purpose of the Crothall Patent. The Crothall Patent is cited as disclosing a porous sheath to protect a sensor from troublesome tissue and debris. The intended function of the sensor in the Crothall Patent is to be implanted in a mammal without a catheter so that the chemical composition of blood can be monitored. See Column 6, Line 15-16. If the sensor of the Crothall Patent were combined with the catheter of the Millar Patent, the intended function of the Crothall sensor would be destroyed. As such, one of skill in the art would not reason to combine the Crothall Patent and the Millar Patent as the intended function of the Crothall Patent would be destroyed.

As the Millar Patent and the Crothall Patent cannot be properly combined as the combination would destroy the intended function of the Crothall patent, Applicants request withdrawal of the 103 rejection of claims 31, 34, 36 and 39.

7. Claims 31-33 and 36-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Kovacs Patent in view of the Knute Patent and in further view of the Crothall Patent. As stated in the Office Action, the combination of the Knute Patent and the Kovacs Patent does not teach at least one sensor capable of sensing pH located within a porous sheath.

As stated above, if a combination of prior art references destroys the purpose or function of the prior art reference or references, one of ordinary skill in the art would not have found a reason to make the combination. In re. Gordon, 733 F.2d 900 (Fed. Cir. 1984). Combining the Crothall Patent with the Knute Patent destroys the intended purpose of the Crothall Patent. As stated above, the Crothall Patent is cited as disclosing a porous sheath to protect a sensor from troublesome tissue a debris. The intended function of the sensor in the Crothall Patent is to be implanted in a mammal without a catheter so that the chemical composition of blood can be monitored. See Column 6, Line 15-16. If the sensor of the Crothall Patent were combined with the catheter of the Knute Patent, the intended function of the Crothall sensor would be destroyed. As such, one of skill in the art would not reason to combine the Crothall Patent and the Knute Patent as the intended function of the Crothall Patent would be destroyed.

As the Knute Patent and the Crothall Patent cannot be properly combined as the combination would destroy the function of the Crothall Patent, Applicants request withdrawal of the 103 rejection of claims 31-33 and 36-38.

8. Claims 35 and 40 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Kovacs Patent in view of the Knute Patent and further in view of the Crothall Patent and further in view of the Bentson and Lubbers Patents. As discussed above, the Knute Patent and the Crothall Patent cannot properly be combined as the combination would destroy the function of the Crothall patent. As such, Applicants request withdrawal of the 103 rejection of claims 35 and 40.

Applicant respectfully submits that the application is in condition for allowance and requests a timely notice of allowance be issued. The present Amendment is being filed concurrently with a Request for Continued Examination and a check for \$385 which represents the Request for Continued Examination fee pursuant to 37 C.F.R. §1.17(e) for a small entity. Should any unresolved issues remain in the case, please feel free to contact the undersigned at the telephone number listed below.

Respectfully submitted,



William B. Kircher  
Reg. No. 22,481

WBK:nlm

SHOOK, HARDY & BACON, L.L.P.  
One Kansas City Place  
1200 Main Street  
Kansas City, Missouri 64105-2118  
Tel.: 816/474-6550  
Fax: 816/421-5547